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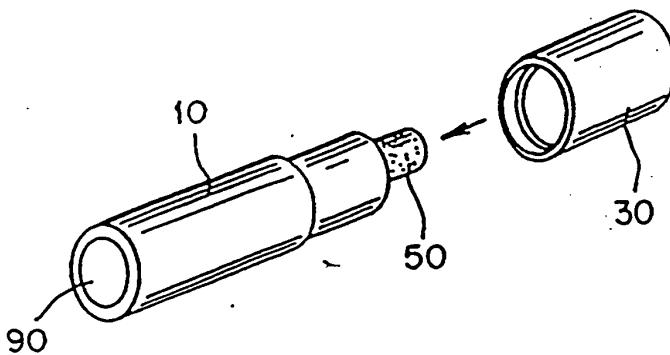
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: <b>G01N 21/00</b>	A1	(11) International Publication Number: <b>WO 95/08761</b> (43) International Publication Date: <b>30 March 1995 (30.03.95)</b>
(21) International Application Number: <b>PCT/US94/10434</b>		(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: <b>14 September 1994 (14.09.94)</b>		Published <i>With international search report.</i>
(30) Priority Data: <b>08/124,106 20 September 1993 (20.09.93) US</b>		
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(54) Title: ANALYTICAL TEST FORMATS AND METHODS OF CONDUCTING ANALYTICAL TESTS

## (57) Abstract

An analytical test format and methods of conducting analytical tests are disclosed. One embodiment comprises an analytical test format having a wicking portion (50) which is moveable relative to a support structure (10). According to another embodiment, the test format is substantially biodegradable. Methods disclosed herein comprise exposing a collection portion of said wick by moving the collection portion relative to a support structure.



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## ANALYTICAL TEST FORMATS AND METHODS OF CONDUCTING ANALYTICAL TESTS

The present invention is directed to analytical testing and, more particularly, to analytical test formats and methods of conducting analytical tests.

### Background of the Invention

Rapid assay testing has become very popular in recent years. Biological and chemical test devices have been developed for use in the home or in the field to provide quick and sufficiently accurate results even when the analysis is conducted by untrained persons. For example, pregnancy and ovulation test formats have been developed on which a single sample is collected, typically in a specimen container, and then poured into an opening of an analytical test format. The analyte in the specimen is transferred to a reaction site where the presence of the analyte will be indicated by some visible indicia. Typically, a liquid specimen, such as urine, is applied to an inlet of the analytical test format where the subject analyte binds to an antibody, and the analyte-antibody complex is carried along a nitrocellulose wick by capillary action to a reaction site. At the reaction site, the complex contacts an analyte-specific antibody which produces a discrete visible indication. As a built-in procedural control, the analytical test format may also be designed to provide a different visible indication if the specific analyte-antibody complex is not formatted in order to indicate a valid negative test.

An advantage of presently known systems is their ability to store non-liquid chemistries and thereby provide a long shelflife for the test formats. One disadvantage of known test formats is that their size makes them difficult to conceal when desired for discrete use. Furthermore, since it is often desirable to prevent the flooding of a test site with the liquid sample, some test formats have been designed with sample overflow chambers. Such overflow chambers complicate the design of the test formats and generally increase the cost of production. The size and increased quantity of test formats used in recent years has also added to the global problem of waste disposal.

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In light of the increased popularity of over-the-counter analytical test formats, it has become desirable to provide a test format which exhibits greater control over the amount of specimen collected by the device. Those skilled in the art will appreciate that if a test format can be provided which carefully limits the amount of specimen liquid which can be added to the test format, the risk of flooding the reaction site will be reduced. Such a test format would eliminate the need for overflow chambers, as well as their inherent cost and size disadvantages.

It is also particularly desirable to provide a test format which can be carried in a very discrete fashion. For example, a woman conducting a pregnancy or ovulation test may, wish to keep the fact that she is conducting the test confidential. Therefore, it is desirable to provide a test format which is relatively small and can be used in a very discrete fashion.

Furthermore, in light of the many uses of analytical test formats, including uses outside of the medical field, it is particularly desirable to provide one-step analytical test formats which are biodegradable. Such biodegradable test formats would be particularly useful when testing is conducted in a restroom environment or as an environmental test in the outdoors. These and other advantages are realized by the analytical test formats and methods of the present invention.

#### Summary of Invention

One embodiment of the present invention is designed to provide an improved analytical test format which is advantageously smaller than previously known test formats and can, therefore, be used in a more discrete manner. This embodiment is also designed to provide greater control over the amount of specimen collectable by the test format even when used by untrained people. This embodiment advantageously comprises a support structure having a substantially hollow interior portion and a wick which is at least partially disposed within the hollow interior portion and is movable relative to the support structure. According to this embodiment of the present invention, the wick is designed to be placed in a flowing stream of the test specimen.

Once the wick has become saturated, excess liquid specimen will flow over the wick and will not be collected by the test format. The risk of flooding the reaction site and adversely effecting the accuracy of the test is thereby reduced.

Another embodiment of the present invention is specifically designed to have a minimal environmental impact after use. This embodiment is formed of biodegradable components, specifically a biodegradable support structure, a biodegradable wick, and a biodegradable membrane comprising a reaction site on which the specific antibody or DNA probe is attached to link with the hormones or bacteria in the sample analyte.

One preferred embodiment of the present invention comprises the advantages of compactness and biodegradability in an analytical test format formed substantially of biodegradable materials with a wick that is movable relative to a support structure.

A still further embodiment comprises a compact test format with a support structure which is foldable into an overlapping configuration and a wick which causes a liquid specimen to flow in a tortuous path from an exposure area to a reaction site.

The present invention also comprises methods of conducting biological and chemical analytical tests. These and other embodiments are described in further detail below.

#### Brief Description of the Drawings

Figure 1 is a partially-explored, perspective view of one embodiment of the present invention.

Figure 2 is a partially-explored, perspective view of the test format illustrated in Fig. 1 with the wick in an exposed position.

Figures 3 and 4 are cross-sectional views of the test format shown in Fig. 1.

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Figure 5 is a cross-sectional view of the wick and test site of the embodiment shown in Fig. 1.

Figure 6 is a partial cross-sectional view of an alternative embodiment of the present invention.

Figure 7 is a cross-sectional view of a still further embodiment of the present invention.

Figure 8 illustrates an alternative embodiment of the present invention wherein a wick is pivotally rotatable relative to a support structure.

Figures 9 and 10 illustrate still further embodiments of the present invention.

Figure 11 illustrates an embodiment designed to puncture a barrier in order to draw a liquid test specimen.

Figures 12 and 13 illustrate a still further embodiment wherein the test sample follows a tortuous path to the reaction site.

#### Detailed Description

The test formats of the present invention are designed to quickly provide qualitative and/or quantitative test results even in the hands of untrained users. The disclosed analytical test formats are also specifically designed for relatively simple, inexpensive manufacturing.

One embodiment of the present invention is illustrated in Figs. 1-5. This embodiment comprises a support structure 10, a removable cap 30, and a wick 50. In this illustrated embodiment, the removable cap 30 is designed to fit over one end, herein referred to as the "collection end", of support structure 10 covering an exposed portion of wick 50 as best shown in Fig. 4. Cap 30 is also designed to attach to the

opposite end, herein referred to as the "observation end", of support structure 10 during a testing procedure in the manner illustrated in Fig. 3.

Though the support structures of the present invention can have a wide variety of shapes and sizes, this illustrated embodiment is substantially cylindrical. The illustrated support structure 10 comprises a collection end with sidewalls 12 which define an opening through which wick 50 is selectively movable. In this embodiment, wick 50 is initially positioned with a small portion disposed outside of sidewalls 12 allowing the wick to be grasped between the thumb and forefinger and drawn out of the hollow interior portion of support structure 10. The extent to which wick 50 can be exposed is controlled by the placement of a stop ring 70. In the illustrated embodiment, ring 70 is positioned at the distal end of wick 50 thereby allowing most of wick 50 to be drawn out of the hollow interior chamber of support structure 10 and exposed to a test specimen. Stop ring 70 can be attached to wick 50 in any suitable manner which will not interfere with the chemistry of the analytical test. For example, if test ring 70 and wick 50 are formed of conventional plastics, ring 70 can readily be attached by ultrasonic welding. Stop ring 70 also prevents any excess specimen from entering the interior of support structure 10 when the wick 50 is positioned in the distal "exposed" position.

In this illustrated embodiment, a reaction site is advantageously positioned on the distal portion of wick 50 which remains within the hollow interior portion of support structure 10. The illustrated reaction site comprises a membrane 80 comprising suitable reactive compounds. The membrane 80 is maintained in position on wick 50 by ring 70. The distal end of support structure 10 comprises an observation window 90 through which the reaction results can be observed.

Those skilled in the art will appreciate that a variety of reactive compounds are available for use in conducting different tests. Compounds are preferably selected which will provide a visible indication of the presence of a specific analyte within minutes of exposing the proximal end of wick 50 to a specimen stream. All embodiments of the present invention are designed for use with a wide variety of

analytical test chemistries. For example, the analytical test formats disclosed herein are useful for medical diagnostics, detection for drugs of abuse, agricultural and environmental testing. Those skilled in the art will appreciate that the field of chemical and biological testing has grown significantly in recent years and will continue to develop. The various embodiments of the present invention provide methods and test formats suitable for a wide range of these uses.

In use, cap 30 is removed from the exposure end of support structure 50 and can be conveniently positioned over the observation end covering observation window 90. The exposed portion of wick 50 can then be grasped by the user and withdrawn to a predetermined extent as determined by the positioning of stop ring 70. The exposed portion of wick 50 is then advantageously contacted with a specimen stream, for example, urine. While holding support structure 10 with one hand, cap 30 can be removed with the tester's other hand, placed over the distal end of wick 50 and used to force wick 50 back into the hollow interior portion of support structure 10. The collected specimen will then be drawn through wick 50 to reaction site 80. Those skilled in the art will appreciate that the liquid specimen will be drawn by capillary action through wick 50. In order to provide the greatest control over the flow of liquid specimen through wick 50, after cap 30 is replaced on the collection of support structure 10, the entire test format is preferably disposed vertically with observation window 90 positioned at the top of the test format and the end of cap 30 resting on a horizontal surface. This method advantageously utilizes gravity to decrease the rate of specimen flow through the remainder of wick 50.

The material(s) and method(s) used in forming wick 50 are preferably selected to control the rate of flow of the liquid specimen and also the degree of filtering desired. Those skilled in the art will appreciate that undesired particles, such as crystals or other substances can be selectively filtered from the specimen before the specimen reaches reaction site 80 by appropriately designing wick 50. The density of the wick 50 which is controlled in part by the pressure applied to wick 50 during manufacture, will affect the rate of flow of a liquid specimen in the direction of reaction site 80.

The illustrated embodiment is merely exemplary and is not intended to limit the scope of the present invention. For example, the reaction site 80 is not necessarily disposed on the distal end of wick 50. An alternative design comprises disposing reaction site 80 on the support structure 10 proximate observation window 80. In this manner, the liquid specimen can only reach the reaction site after the wick 50 has been fully re-inserted into the hollow interior portion of support structure 10.

Figure 6 illustrates an alternative manner of controlling the displacement of a wick relative to a support housing. According to the embodiment illustrated in Figure 6, a cap 130, similar to cap 30 discussed above, is positionable upon the proximal end of the test format in a manner which covers observation window 190 and fictionally engages a rotatable flange 140. Flange 140 is connected to a cylinder 120 having a longitudinal slot through which guide pins 160 move longitudinally as flange 140 is rotated relative to housing 110. As illustrated, housing 110 is provided with internal threads which cause guide pins 160, and consequently wick 150, to move in the distal direction, i.e. away from rotatable flange 140 as rotatable flange 140 is rotated relative to housing 110,. In general, this embodiment somewhat resembles a lipstick container wherein wick 150 moves relative to housing 110 in the same manner that lipstick moves relative to the lipstick container.

The method of using the embodiment of the present invention illustrated in Figure 6 is similar to that described above wherein cap 130 is removed from the exposure end of housing 110 (not shown) and placed on the observation end over rotatable flange 140. The exposed portion of housing 110 is grasped in one hand while cap 130 is rotated causing guide pins 160 to travel within the internal threaded grooves 115 of housing 110 thereby moving wick 150 distally relative to housing 110. After the distal end of wick 150 has been exposed to the specimen, the steps are reversed and wick 150 is drawn back into the proximal end of housing 110 and cap 130 is returned to the distal end of the housing 110. After the sample has moved through wick 150 to reaction site 180, the test results can be readily observed through observation window 190. This embodiment of the present invention advantageously eliminates the need for a person to contact the wick at any time during the test procedure. This embodiment

is particularly useful for testing liquid specimens which may pose health hazards or are otherwise unsuitable for contact with the user's hand.

According to a still further embodiment of the present invention, a plurality of reaction sites may be disposed along the length of the wick or along the support structure on portions contacted by the wick. A plurality of such reaction sites can be employed to conduct a series of tests utilizing a single test format. Figure 7 illustrates an alternative embodiment of the present invention comprising a plurality of test sites 280 located on the side of a support structure 210. According to this embodiment, a proximal portion of wick 250 contacts the interior side of reaction sites 280 when wick 250 is in the "non-exposed" position. Figure 7 also indicates a degree of variability inherent in the present invention which allows the analytical test format to be larger for other uses. For example, the wick can be formatted with a proximal point and with a sufficient degree of rigidity to allow the insertion of the wick into an object or matter, e.g. soil for an environmental test. The wick 250 and housing 210 may be formed with any suitable length depending on the test to be performed, e.g. 6 to 12 inches in order to permit the insertion of the wick into soil for testing below the ground surface. Sidewalls 212, cap 230, and stop ring 270 are similar to the corresponding elements described above.

Figure 8 illustrates a still further embodiment of the present invention wherein a wick 350 having a generally rectangular cross section is rotatably disposed within a protective housing 310. Wick 350 is rotatably connected to housing 310 by a pivot pin 312. While the wick 350 may normally be disposed within housing 310, during testing the wick 350 is rotated out of housing 310 to the configuration illustrated in Figure 8 and the exposed portion of wick 350 is contacted with the test sample. The wick 350 is then preferably rotated back into housing 310. As the specimen moves through wick 350 into the portion of wick 350 that had been shielded from the specimen stream, the test specimen will contact the test site located proximate observation window 390. Those skilled in the art will appreciate that by positioning the test site and observation window 390 on a portion of housing 310 corresponding to a portion of wick 350 that was not directly exposed to the liquid specimen, the liquid specimen which reaches the

test site proximate observation window 390 will necessarily travel through a portion of wick 350. In this manner, advantages of the wicking action, such as filtering of the liquid test specimen, can be achieved.

Figure 9 illustrates a further embodiment of the present invention wherein a wick 450 is attached to a button 455 such that button 455 and wick 450 are slidable relative to a housing 410. By sliding button 455 distally relative to housing 410, wick 450 is exposed for contacting with a test specimen. When button 455 is moved proximally relative to housing 410, the wick 450 is withdrawn into an interior space within housing 410. As in the embodiments described above, an observation window 490 is provided proximate a reaction site for observing a visible indication at the reaction site.

A still further embodiment is illustrated in Figure 10 wherein a wick 550 is pivotally connected to a handle 540 and slidably contained in a housing 510. The pivotal connector 530 allows handle 540 to pivot relative to wick 550 in the manner illustrated in the directions indicated by arrow R. When this test format is in the storage position, the portion of handle 540 opposite connector 530 is positioned proximate the distal end of housing 510 close to opening 512, and pivotal connector 530 is positioned at the opposite, proximal end of housing 510. In this position wick 550 is contained within housing 510 and is covered by handle 540. When a person desires to use this test format, wick 550 is exposed by first rotating handle 540 upwardly. Then, the lower portion of handle 540 is urged distally causing pivotal connector 530 to urge wick 550 distally out of housing 510 through opening 512. In order to lock wick 550 in the exposed position, the rotation of handle 540 is continued to position the entire handle 540 within the open recess of housing 510. After wick 550 has been exposed, handle 540 is rotated back to its original position bringing the wick 550 back into housing 510 and thereby contacting a test site 580 located on handle 540 with a proximal portion of wick 550. An observation window 590 is disposed on handle 540 opposite test site 580 to permit visible observation of the reaction site.

A still further embodiment of the present invention is illustrated in Figure 11.

This embodiment is particularly adapted for puncturing a site in order to access a specimen fluid. According to this embodiment, a sharpened cannula 655 is disposed in the distal end of wick 650. The wick 650 of this embodiment is preferably formed of a material which is sufficiently pliable such that pressure applied to the distal end of the wick 650 compresses the wick 650 to expose the sharpened tip of cannula 655. In this manner, cannula 655 is able to puncture many membranes, including skin, in order to expose wick 650 to a liquid specimen. The operation of this embodiment of the present invention is similar to the embodiment illustrated above in Figure 6 wherein rotational movement of housing 610 relative to proximal rotatable flange 640 causes the wick 650 to move longitudinally relative to housing 610. In this embodiment, however, a breakable capsule 685 is optionally positioned at the proximal end of retaining ring 670 such that after wick 650 is exposed to the specimen fluid and wick 650 is drawn back into housing 610, breakable capsule 685 can be broken in order to expose a new reagent to the exposed wick 650. For example, when conducting a blood test for a diabetic, it may be desirable to provide a reagent capable of wetting the blood sample collected at the distal end of wick 650 in order to facilitate the sample's movement to reaction site 680. Those skilled in the art will appreciate that other applications may take advantage of the features of this embodiment of the present invention.

Figures 12 and 13 illustrate a still further embodiment of the present invention wherein a housing 710 is formed with a distal section 711 which is connected by a hinge, for example a living hinge, to a proximal section 712. The top of distal section of housing 711 comprises a window 720 which exposes a portion of a wick 750. As best shown in Figure 13, wick 750 is folded onto itself forming an upper and lower layer separated by an impermeable barrier 755. When the distal end of housing section 711 is exposed to a stream of liquid specimen, the exposed portion of wick 750 contacts the specimen and the specimen travels through wick, e.g. via capillary action, around impermeable barrier 755 to the side of distal housing 711 opposite window 720. When the housing distal section 711 is folded under proximal section 712, test site 780 on proximal housing portion 712 contacts egress window 740 thereby permitting the specimen fluid which has traveled through distal housing section 711 to contact test site 780. Any visible reaction occurring at test site 780 is readily observable through

observation window 790 located on the side of proximal housing section 712 opposite reaction site 780. This embodiment of the present invention advantageously maximizes the amount of wick through which the liquid specimen must travel before reaching the reaction site while minimizing the overall size of this test format. After the test has been performed, this embodiment of the present invention can be discarded as a single unit or the housing portions can be separated forming smaller pieces. Smaller pieces of refuse may be desirable, for example, the test device will be flushed through a waste disposal system.

The materials used in forming the elements of the illustrated embodiments of the present invention can include any materials which will not adversely affect the chemistry of the tests to be conducted. For example, in the embodiment shown in Figures 1-5 the support structure 10, cap 30 and stop ring 70 can be formed of any inert compounds, most preferably a non-absorbent material, such as conventional plastics including polystyrene, coated boards, metals, ceramics, etc. Wick 50 can be formed of such materials known in the art which can carry the liquid specimen to the reaction site, e.g. by capillary action, such as nitrocellulose, polysulphone, nylon, and other materials known to those of ordinary skill in the art. The reaction site 80 can also be formatted of conventional materials such as nylon polysulphone, cellulose acetate, polycarbonate, polypropylene, and specially treated blotting papers.

The embodiment illustrated in Figs. 1-5 can be formatted such that it is small enough to be flushable through conventional residential plumbing. A preferred embodiment comprises a test format formatted of material which will decompose in sewage treatment facilities. For example, the entire test format can have a length of about two inches. Alternatively, similarly structured test formats can be formatted with larger dimensions for other applications. For example, the test format illustrated in Fig. 7 can have a length of about twelve inches to allow the insertion of rigid wick 250 into the ground.

Another preferred embodiment of the present invention comprises a test format formed substantially of biodegradable materials. For example, one preferred

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biodegradable embodiment of the present invention is suitably compact such that after conducting a test procedure, the entire test format can be readily disposed of at the test site. If the test is conducted in a residential bathroom, the entire test format can be formatted so that it is suitable to flushing in a toilet without the risk of clogging the plumbing. Alternatively, if an environmental test is conducted, the entire test format could be simply pushed into the ground where it would break down over an acceptable length of time. Generally speaking, biodegradable materials are those that can be readily broken down into constituent elements that are either beneficial to, or at least not adverse to, the biosphere.

According to this embodiment of the present invention, the test format can have a wide variety of designs and is not limited to the designs illustrated above. By way of example, a rigid support structure can be formed of "biodegradable" materials. An example of a "biodegradable" plastic is NOVON brand biodegradable polymer, a starch-based polymer described in U.S. Patent No. 4,673,438 and U.S. Patent No. 4,738,724, which are incorporated herein by reference. Shaped articles made from such a material can rapidly be broken down in biologically active environments, such as compost facilities and water treatment facilities. The resulting humus may advantageously provide nutrients when applied to soil. Other known biodegradable polymers include polysaccharides, polyvinyl alcohols, polyhydroxyalkanoates, polylactates, polycaprolactone, polyglyconate, bacterial polyeaters, natural proteins and cellulose may be used in part or in total for these shaped articles.

The wick material is also advantageously formed of a biodegradable material such as a cellulose acetate or cellulose mixed esters.

Another aspect of the present invention comprises a method of conducting an analytical test comprising the steps of:

(1) providing an analytical test format comprising:

a support structure having a substantially hollow interior portion; and

a wick at least partially disposed within

said hollow interior portion and movably disposed relative to said support structure to enable at least a portion of said wick to be moved outside of said hollow interior portion;

- (2) exposing a collection portion of said wick by moving said collection portion from said hollow interior portion of said support structure; and
- (3) contacting said collection portion of said wick with an analyte.

One preferred form of this method comprises the step of providing a biodegradable support structure and/or a biodegradable wick.

**CLAIMS.**

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- 1      1. An analytical test format comprising:
  - 2            a support structure having a substantially hollow interior portion;
  - 3            a wick at least partially disposed within said hollow interior portion and
  - 4            movably disposed relative to said support structure to enable at least a portion of said
  - 5            wick to be moved outside of said hollow interior portion.
- 1      2. An analytical test format according to claim 1 further comprising means for  
2            providing visible indicia of the presence of an analyte, said indicia providing means  
3            disposed in fluidic communication with said wick during at least a portion of an  
4            analytical procedure.
- 1      3. An analytical test format according to claim 2 wherein said indicia providing  
2            means is connected to said wick.
- 1      4. An analytical test format according to claim 2 wherein said indicia providing  
2            means is connected to said support structure.
- 1      5. An analytical test format according to claim 1 further comprising means for  
2            restricting movement of said wick out of said hollow interior portion.
- 1      6. An analytical test format according to claim 5 wherein said restricting means is  
2            connected to said wick.
- 1      7. An analytical test format according to claim 1 wherein said wick is initially  
2            positioned in a storage position with a first portion of said wick extending out of said  
3            hollow interior  
4            portion and wherein said wick is movable to an exposure position where a greater  
5            portion of said wick extends out of said hollow interior portion.
- 1      8. An analytical test format according to claim 7 further comprising a cap  
2            removably connected to said support structure for covering said wick when said wick  
3            is in said storage position.

1        9. An analytical test format according to claim I wherein said support structure is  
2        formed of a biodegradable material.

1        10. An analytical test format according claim 9 wherein said wick is formatted of  
2        a biodegradable material.

1        11. An analytical test format according claim 9 wherein said support structure is  
2        formed of a material selected from the group consisting of starch-based polymers,  
3        polysaccharides, polyvinyl alcohols, polyhydroxyalkanoates, polylactates,  
4        polycaprolactone, polyglyconate, bacterial polyesters, natural proteins and cellulose.

1        12. An analytical test format according to claim I wherein said wick is threadably  
2        connected to said support structure.

1        13. An analytical test format according to claim 1 wherein said support structure is  
2        substantially oblong comprising a first end having an opening through which said wick  
3        is selectively movable and a second end region comprising a transparent window.

1        14. An analytical test format according to claim 1 wherein said wick is rotatably  
2        connected to said support structure.

1        15. An analytical test format according to claim 14 wherein said wick is rotatable  
2        from a first position where said wick is substantially covered by said support structure  
3        to a second  
4        position where said wick is exposed.

1        16. An analytical test format according to claim 15 further comprising means for  
2        providing visible indicia of the presence of an analyte, said indicia providing means  
3        disposed on said support structure and aligned with a portion of said wick, when said  
4        wick is in said first position, which is not exposed when said wick is in said second

5 position.

1 17. An analytical test format according to claim 1 further comprising a sharpened  
2 cannula connected to said wick.

1 18. An analytical test format according to claim 1 comprising a plurality of means  
2 for providing indicia of the presence of an analyte.

1 19. A biodegradable analytical test format comprising:  
2 a biodegradable support structure; a biodegradable wick connected to said  
3 support structure; and  
4 a means for providing visible indicia of the presence of an analyte, said  
5 indicia providing means disposed in fluidic communication with said wick during at  
6 least part of an analytical procedure.

1 20. A biodegradable analytical test format according to claim 19 wherein said  
2 support structure comprises a substantially hollow interior portion; and  
3 wherein said wick is at least partially disposed within said hollow interior  
4 portion and is movably disposed relative to said support structure.

1 21. A biodegradable analytical test format according to claim 19 wherein said  
2 support structure is formed of a material selected from the group consisting of starch-  
3 based polymers,  
4 polysaccharides, polyvinyl alcohols, polyhydroxyalkanoates, polylactates,

5 polycaprolactone, polyglyconate, bacterial polyesters, natural proteins and cellulose.

1 22. A biodegradable analytical test format according to claim 19 wherein said wick  
2 is formed of a material selected from the group consisting of starch-based polymers,  
3 polysaccharides, polyvinyl alcohols, polyhydroxyalkanoates, polylactates,  
4 polycaprolactone, polyglyconate, bacterial polyesters, natural proteins and cellulose.

1 23. A biodegradable analytical test format according to claim 19 wherein said test  
2 format is flushable.

1 24. A method of conducting an analytical test comprising the steps of:  
2 providing an analytical test format comprising:  
3 a support structure having a substantially hollow interior portion;  
4 a wick at least partially disposed within said hollow interior portion and movably  
5 disposed relative to said support structure to enable at least a portion of said wick to  
6 be moved outside of said hollow interior portion;  
7 exposing a collection portion of said wick by moving said collection portion  
8 from said hollow interior portion of said support structure; and  
9 contacting said collection portion of said wick with an analyte-

1 25. A method of conducting an analytical test according to claim 24 wherein said  
2 step of providing a support structure comprises providing a biodegradable support  
3 structure.

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**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) : G01N 21/00  
 US CL : 422/55, 56, 58, 61, 68, 86

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 422/55, 56, 58, 61, 68, 86

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
 NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
 NONE

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO, A, 85/04255 (BLAKE ET AL.) 26 September 1985. See entire disclosure.	1-29

Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents:

"A"	document defining the general state of the art which is not considered to be of particular relevance	T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier document published on or after the international filing date	X	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	Y	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed	&	document member of the same patent family

Date of the actual completion of the international search

20 DECEMBER 1994

Date of mailing of the international search report

11 JAN 1995

Name and mailing address of the ISA/US  
 Commissioner of Patents and Trademarks  
 Box PCT  
 Washington, D.C. 20231

Faximile No. (703) 305-3230

Authorized officer

AMALIA SANTIAGO

Telephone No. (703) 308-0196

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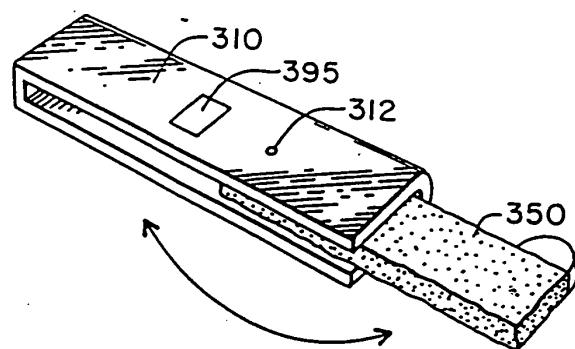


FIG. 8

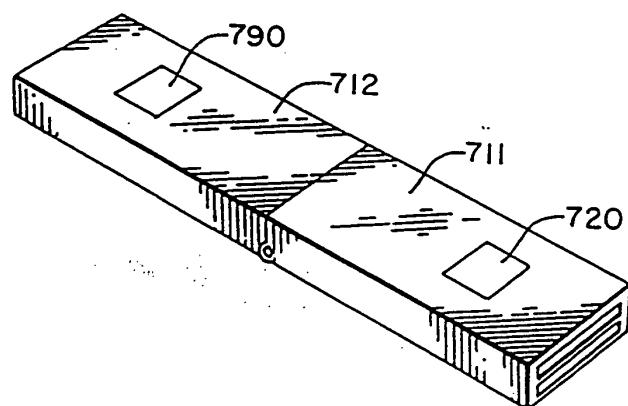


FIG. 12

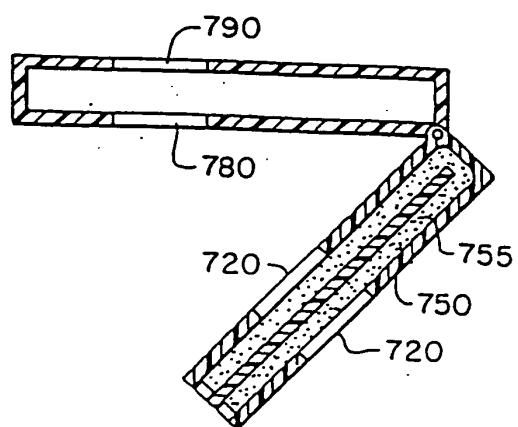
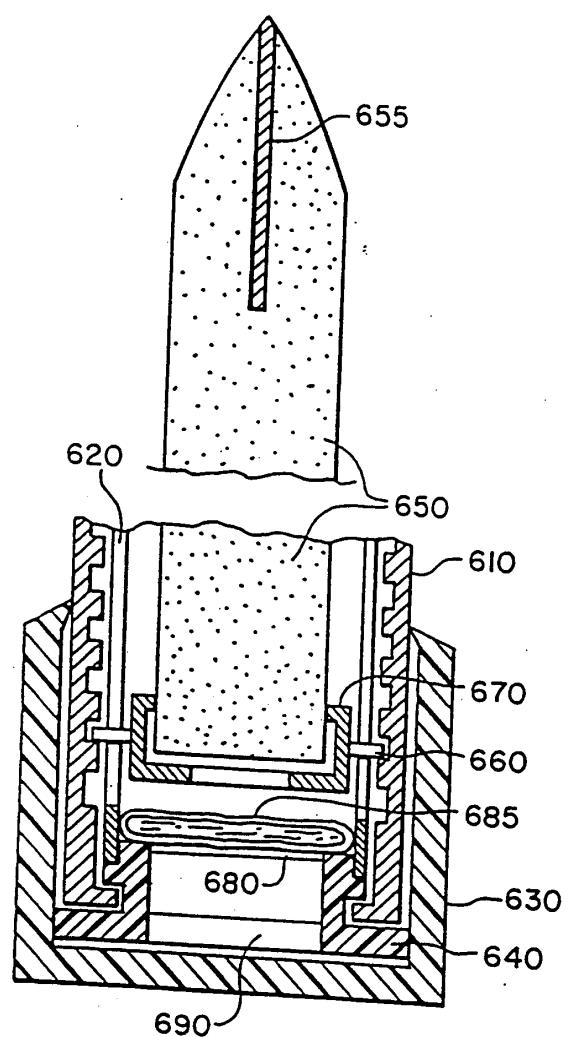


FIG. 13

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*FIG. II*

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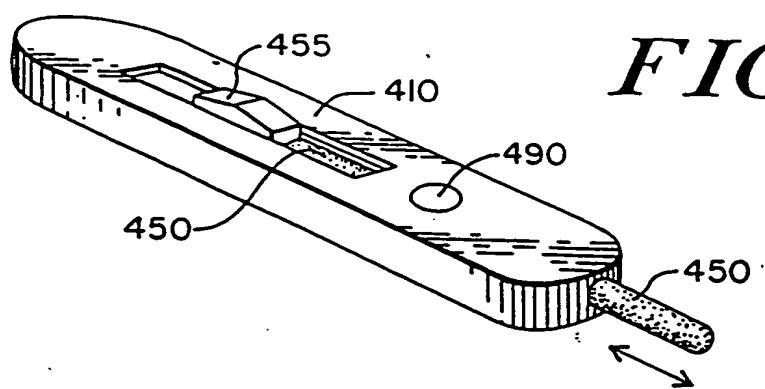


FIG. 9

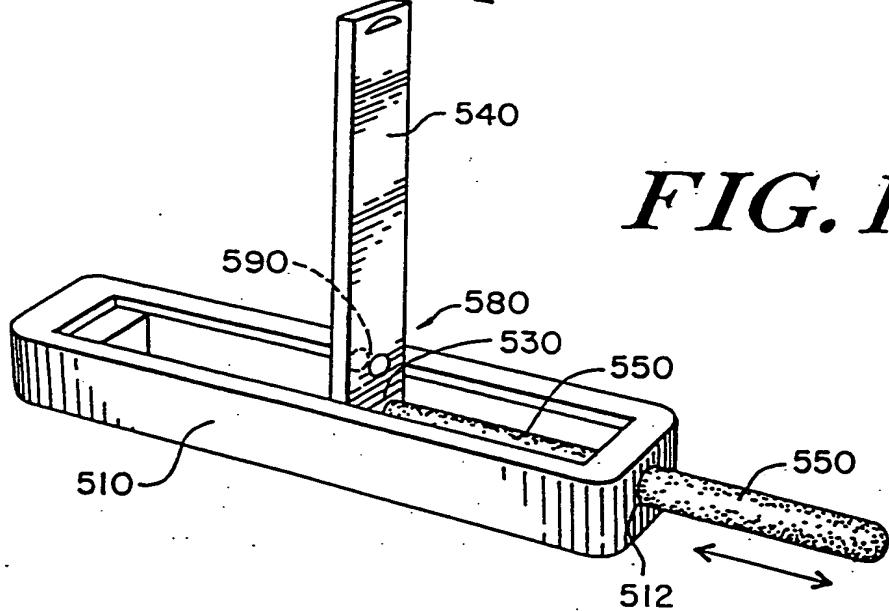


FIG. 10

FIG. 5

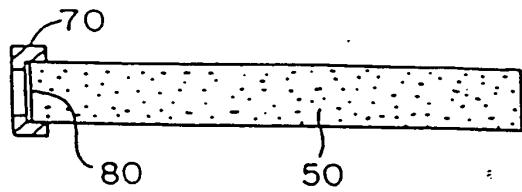


FIG. 6

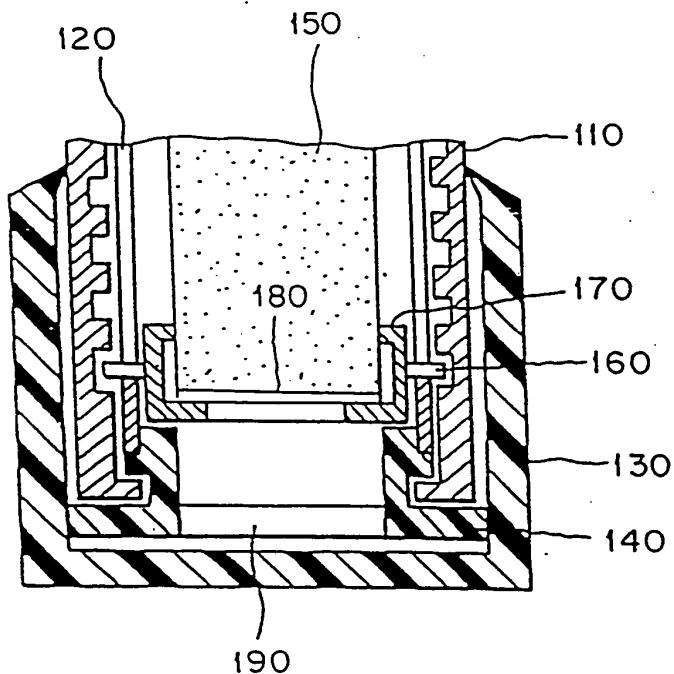
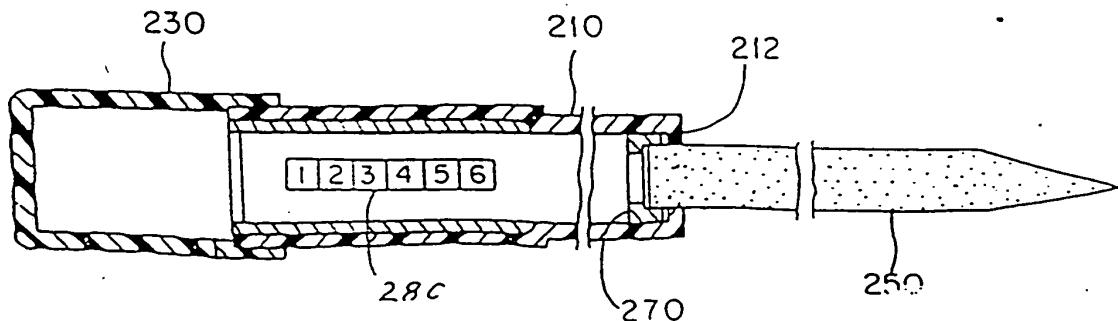


FIG. 7



SUBSTITUTE SHEET (RULE 26)

1/5

FIG. 1

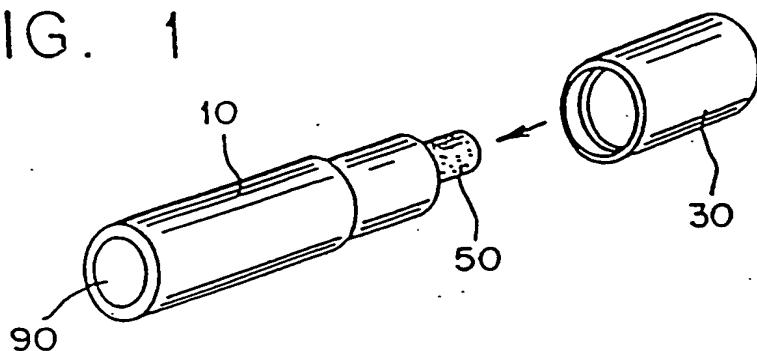


FIG. 2

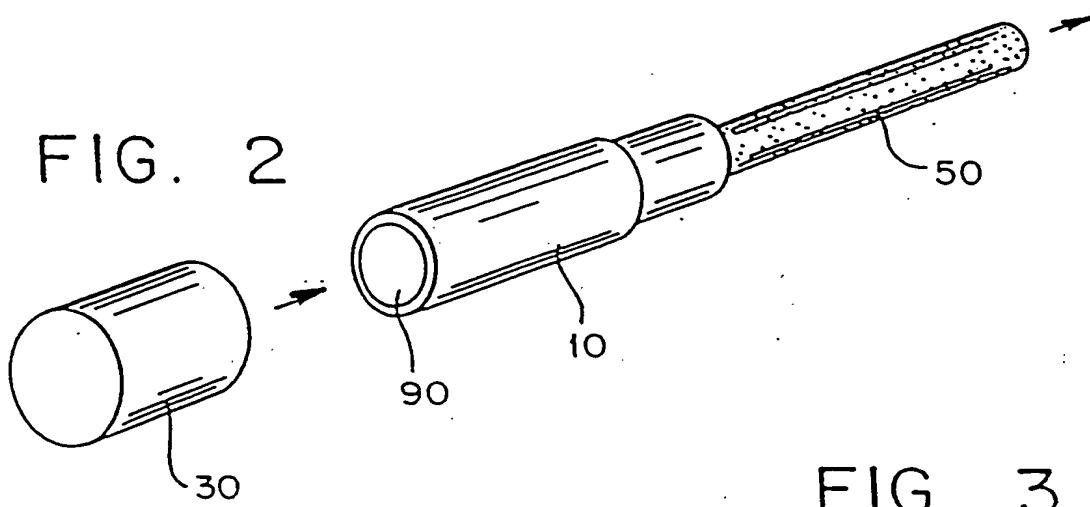


FIG. 3

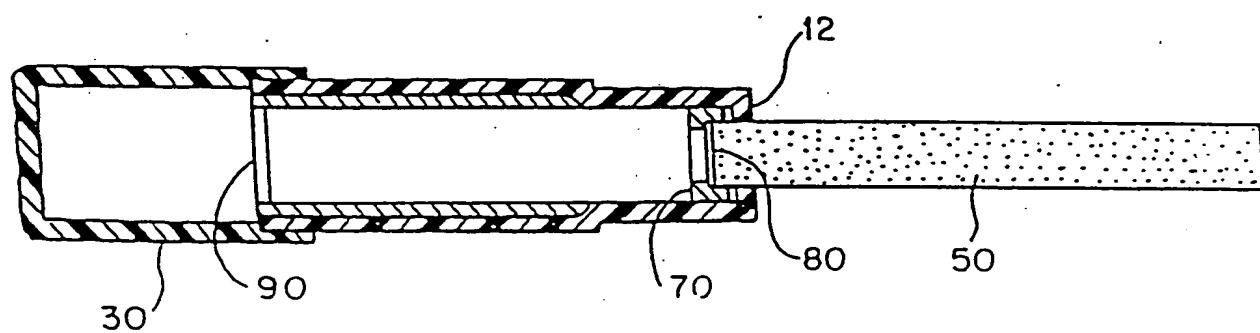


FIG. 4

